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Food Safety And Inspection Service
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AUDIT REPORT FOR ICELAND
OCTOBER 9 THROUGH OCTOBER 18, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Iceland's meat inspection system from October 8 through October 18, 2001. Five establishments are certified to export meat to the United States and all were audited. All of these were slaughter establishments and conduct some further processing.

The last audit of the Icelandic meat inspection system was conducted in October 2000. Five establishments were audited and all were acceptable. These establishments were 22, 23, 31, 40 and 81. The following concerns were reported at that time: HACCP was poorly understood in all plants, especially the measurement of critical control limits, and pre-shipment review was not being done in any plants. The residue control program had an excessive turn-around time for results being in excess of four months. Species testing on finished product was not being done.

Iceland is eligible to export beef, pork and sheep meat to the United States at this time.

From January to September 30, 2001, Iceland establishments exported nearly 5,000 pounds of lamb to the U.S. Port-of-entry rejections were for missing shipping marks (0.6%).

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Icelandic national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. The third was conducted by on-site visits to establishments. The fourth was a visit to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other conducting species testing on finished product and antibiotic screening tests. A farm was also visited and questions were asked about the use of antibiotics, vaccines and other chemical compounds and the procedures in place to prevent these chemicals from entering the food chain.

Iceland's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials. (This was the case with one establishment—see below.)

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in four of the five establishments audited. One establishment (40) was found to be unacceptable. Details of audit findings, including compliance with HACCP, SSOPs, and testing program for generic *E. coli,* are discussed later in this report.

As stated above, some concerns had been identified during the last audit of the Icelandic meat inspection system, conducted in October 2000. During this new audit, the auditor determined that these concerns had been addressed and corrected with the exception of pre-shipment review, which was still not being done.

Entrance Meeting

On October 9, 2001, an entrance meeting was held in the Reykjavik offices of the Icelandic Meat Inspection Division of the Ministry of Agriculture, and was attended by Dr. Sigurður Örn Hansson, Chief of Iceland Meat Inspection; Mr. Edwin Brown, Economic/Commercial Officer, U. S. Embassy; Ms. Borghildur Magsúsdóttir, Assistant Economic/Commercial Officer, U.S. Embassy and Dr. M. Douglas Parks, International Audit Staff Officer, USDA.

Topics of discussion included the following:

1. Audit itinerary.
2. Species testing of finished product.
3. Animal disease status.
4. Compliance and enforcement of meat regulations.
5. Subjects to be covered on the audit (SSOP, HACCP and generic *E. coli* testing).

6. Farm visit, the national residue program and the turn around time for residue sample results.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Iceland's inspection system in October 2000.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of inspection system documents at the time of the on-site audit. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel.
- Label approval records such as generic labels, and animal raising claims.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs and generic *E. coli* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

No concerns arose as a result the examination of these documents.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Iceland as eligible to export meat products to the United States were full-time Inspection Service employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Five establishments were certified to export meat products to the United States at the time this audit was conducted. All five establishments were visited for on-site audits. In four of the five establishments visited, both Iceland Inspection Service inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories, and *intra*-laboratory quality assurance procedures, including sample handling and methodology.

The Icelandic Fisheries Laboratory in Reykjavik was audited on October 9, 2001. Except as noted below, effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done.

The Institute for Experimental Pathology Laboratory in Reykjavik was audited on October 17, 2001. This laboratory does species testing of finished product samples sent from the exporting establishments each month that product for export to the U.S. is produced. It also does microbiological screening tests for antibiotic residues on samples sent from the exporting establishments as directed by the national residue program. Any positive screen test is sent to Denmark for identification of the antibiotic residue. Results are returned in about two weeks.

The check sample program for both laboratories did meet FSIS requirements. Some substances used for standard solutions preparation were outdated and daily working solutions were not dated in the Fisheries Laboratory and the *Bacillus* spores used for the screen tests were outdated at the Pathology Laboratory.

Microbiological testing for *Salmonella* is not applicable in Iceland, as sheep products are the only meat products exported to the United States. Generic *E. coli* testing for minor species is done in private laboratories in the slaughter establishments.

Establishment Operations by Establishment Number

The following operations were being conducted in the five establishments:

Beef, sheep, swine and horse slaughter and boning – two establishments (23 and 81)
Beef, sheep and horse slaughter and boning – one establishments (22)
Beef, sheep and swine slaughter and boning—one establishment (40)
Sheep slaughter and boning—one establishment (31)

SANITATION CONTROLS

Based on the on-site audits of establishments, Iceland's inspection system had controls in place for water potability, chlorination procedures, back siphonage prevention, hand washing facilities, sanitizers, pest control program and monitoring, temperature control, lighting, operations work space, inspector work space, and ventilation.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements, with only occasional minor variations, except in Establishment 40. In Establishment 40, there was a major problem with condensation falling on exposed carcasses in the carcass cooler. Condensate, from overhead structures not cleaned and sanitized daily was falling on approximately 25% of 450 carcasses in the cooler. These carcasses were removed to another area and trimmed before going to the boning room.

Cross-Contamination

The bung dropping procedure on the lamb slaughter lines of four of the five establishments visited was resulting in fecal contamination. However, contamination was being trimmed prior to the CCP for zero tolerance. These were Establishments 22, 31, 40 and 81. A different procedure will be investigated as soon as possible, was the commitment by the inspection officials.

Product Handling and Storage

Meat products in plastic bags were found to be stored on the floor of the freezer in Establishment 40. This will be remedied very soon.

Personnel Hygiene and Practices

The procedures for personnel hygiene were in place in all establishments and were effective.

The sanitation control findings that are of major concern, and the proposed actions are as follows:

1. Bung drop procedure—A new system will be devised as soon as possible in all plants.
2. Condensate falling on exposed product—The carcasses were removed to another area and trimmed. The cause in Establishment 40 was a switch that was turned off by unauthorized personnel. The switch will be secured.
3. Over-spray at the carcass wash in the slaughter department was falling from overhead structures onto exposed carcasses in two establishments (40 and 81). The procedure was changed to prevent this from happening.
4. The final trim station was not properly manned due to an accident (Est. 22) or the trimming was not completely effective (Ests. 81 and 23). These problems were given attention and solved at once and will have closer supervision in the future.

ANIMAL DISEASE CONTROLS

Iceland's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

There is one area of concern in the slaughter area pertaining to post mortem procedures. The heads of all lambs slaughtered are removed after bleeding and are not available for diagnosis and veterinary disposition with the carcass.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

All animals in Iceland have individual identification for trace back of disease and residue.

RESIDUE CONTROLS

Iceland's National Residue Testing Plan for 2001 was being followed, and was on schedule. The Icelandic inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

A sheep farm near Hvammstangi was visited and the owner and wife were interviewed along with their attending veterinarian. The Chief of Meat Inspection, Dr Sigurd Hansson was also present. There was mandatory individual animal identification soon after birth. Tags and ear cuts or notches insure trace back of any animal to its origin. There is almost no movement of livestock from farm to farm and it is closely regulated by Icelandic law. All antibiotics,

vaccines and other chemicals are only sold on the veterinarian's prescription and each carries a withdrawal notice from the veterinarian. Each treatment is recorded and the books were complete and up-to-date. There are no central markets for livestock in Iceland so all are sold directly to the slaughtering establishment.

SLAUGHTER/PROCESSING CONTROLS

The Icelandic inspection system had controls in place to ensure adequate ante-and post-mortem inspection procedures and dispositions, control and disposition of dead, dying, diseased or disabled animals, humane handling and slaughter and disposition of inedible materials generated in the establishments.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements with the following exceptions:

1. Critical control limits were not measurable for one CCP (dirt on wool) in all establishments, they were judgmental. The critical control points that were involved were changed to control points (CP) or good manufacturing procedures (GMP).
2. Preventative actions were not recorded in Establishments 40, 81 and 23. These were initiated immediately.
3. Verification procedures were not written into the program in Establishments 31, 23 and 22. This was corrected immediately.
4. Pre-shipment review was not done in all establishments audited. The procedure is now being done in all establishments as a result of this audit.

Testing for Generic *E. coli*

Iceland has adopted the FSIS regulatory requirements for generic *E. coli* testing.

All five of the establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements with one exception:

1. Two establishments were using testing methods that were neither AOAC approved nor were the procedures submitted for an equivalence determination. The testing methods will be submitted as soon as possible for that determination.

Additionally, establishments had adequate controls in place to prevent meat products intended for Icelandic domestic consumption from being commingled with products eligible for export in the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

With the exception of the unacceptable establishment (Est. 40), the Icelandic inspection system controls [control of restricted product and inspection samples, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock or poultry from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other counties for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources

Testing for *Salmonella* Species

Salmonella testing is not required in Iceland's establishments that are certified to export meat products to the United States because Iceland only exports meat from sheep and FSIS has not established *Salmonella* performance standards for sheep.

Species Verification Testing

At the time of this audit, Iceland was not exempt from the species verification-testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

These monthly reviews were being performed by the Icelandic equivalent of a District Supervisor. He is a veterinarian with many years of experience. Dr. Hansson was in charge of the exporting establishments.

The internal review program was applied equally to both export and non-export establishments. Internal review visits were not always announced in advance but were sometimes unannounced by the reviewer. These reviews are preceded by a letter sent to each establishment once per year. This letter address facilities, equipment and operating conditions in the establishment. These are directed to the 17 District Veterinarians. This letter is followed by an on-site review by the Chief of Meat Inspection one or two times per year. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the central offices in Reykjavik, and were routinely maintained on file for a minimum of 3 years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, an in-depth review is conducted, and the results are reported to Dr. Halldor Runolfsson, Chief Veterinary Officer for evaluation. A plan is formulated for corrective actions and preventive measures.

Enforcement Activities

There have been no formal investigations regarding violations of the legislation of slaughtering, meat processing and meat handling under the jurisdiction of the Veterinary Services during the past year because no violations were revealed. There are no provisions in Icelandic legislation on meat and meat processing which prohibit persons, that have been prosecuted and found guilty of an offense to the legislation, to start working in the meat industry after having served their sentence.

Exit Meeting

An exit meeting was conducted in Reykjavik on October 18, 2001. The participants included Mr. Hakon Sigurgrimsson, Iceland Ministry of Agriculture: Dr. Gisli Sverrir Halldorsson, Iceland Veterinary Officer for Import and Export, Mr. Edwin Brown, Economic/Commercial Officer, U.S. Embassy, Ms. Borghildur Magnusdottir, Assistant Economic/Commercial Officer, U.S. Embassy, and Dr. M. Douglas Parks, International Audit Staff Officer, USDA. The following topics were discussed:

1. Audit results and the delistment of Establishment 40. The required procedures for relistment were discussed and explained to the Icelandic officials.

2. The dropping of lamb heads before veterinary evaluation was discussed. The Iceland officials noted that they would apply for an equivalence determination in the near future to the International Policy Staff.
3. Critical control limits for critical control points were discussed and the officials said that these standards were now better understood and would be changed to proper limits in the future in the HACCP plans of the exporting plants.
4. The requirements for pre-shipment review and the records of the same were discussed and a commitment to assure they are promptly implemented was given by the Icelandic officials.
5. The turn-around time for residue test results was reported to have been reduced from four months to three months.

CONCLUSION

The inspection system of Iceland was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments, except for Establishment 40 which was delisted because of deficiencies revealed during the on-site audit. The concerns noted in the HACCP programs were corrected, as were the deviations in the SSOP program. Commitments were forthcoming from Icelandic officials to correct all of these deviations as soon as possible. A testing method for generic *E. coli* testing will be submitted very soon for an equivalence determination by the International Policy Staff. Five establishments were audited: four were acceptable, and one was unacceptable. The deficiencies encountered during the on-site establishment audits, in those establishments which were found to be acceptable, were adequately addressed to the auditor's satisfaction.

Dr. M. Douglas Parks
International Audit Staff Officer

(signed)Dr. M. Douglas Parks

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing
D. Data collection instrument for *Salmonella* testing *(not applicable)*
E. Laboratory Audit Forms
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
40	√	√	√	√	√	no	no	√
31	√	√	√	√	√	no	√	√
81	√	√	no	√	√	√	√	√
23	√	√	√	√	√	√	√	√
22	√	√	√	√	√	√	√	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. procedures	10.Adequate documentation	11. Dated and signed	12.Pre-shipmt. doc. review
40	√	√	√	√	√	no	√	√	√	√	√	no
31	√	√	√	√	√	√	√	√	no	√	no	no
81	√	√	√	√	√	no	√	√	√	√	√	no
23	√	√	√	√	√	no	√	√	no	no	√	no
22	√	√	√	√	√	√	√	√	no	√	√	no

Attachment C

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is/are being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
40	√	no	no	√	√	√	no	√	√	√
31	√	√	no	√	√	√	no	√	√	√
81	√	√	√	√	√	√	no	√	√	√
23	√	√	√	√	√	√	no	no	√	√
22	√	no	√	√	√	√	no	√	no	√